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EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to L-tyrosine and contribution to normal synthesis of dopamine pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to L-tyrosine and contribution to normal synthesis of dopamine pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)²

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Vitabiotics Ltd. pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to L-tyrosine and contribution to normal synthesis of dopamine. The food constituent, L-tyrosine, is considered to be sufficiently characterised. Contribution to normal synthesis of dopamine is considered to be a beneficial physiological effect. The Panel has already addressed the role of L-tyrosine in the normal synthesis of catecholamines for the general population with a favourable outcome in a previous opinion under Article 13(1) of Regulation (EC) No 1924/2006. L-Tyrosine is the starting point for the synthesis of all catecholamines, including dopamine. The Panel concludes that a cause and effect relationship has been established between the consumption of L-tyrosine in a protein adequate diet and contribution to normal synthesis of dopamine. However, no evidence has been provided that the protein supply in the diet of the European population is not sufficient to fulfil this function of the amino acid. The following wording reflects the scientific evidence: “L-tyrosine contributes to normal synthesis of dopamine”. In order to bear the claim a food should be at least a source of protein as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population. © European Food Safety Authority, 2011

KEY WORDS

L-Tyrosine, dopamine, health claims.

¹ On request from the Competent Authority of the United Kingdom following an application by Vitabiotics Ltd., Question No EFSA-Q-2011-00319, adopted on 30 June 2011.

² Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

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SUMMARY

Following an application from Vitabiotics Ltd., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to L-tyrosine and contribution to normal synthesis of dopamine.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The Panel considers that the food constituent, L-tyrosine, which is the subject of the health claim, is sufficiently characterised.

The claimed effect is “essential for the natural formation of dopamine”. The target population as proposed by the applicant is the general adult population. The Panel considers that contribution to normal synthesis of dopamine is a beneficial physiological effect.

The Panel has already addressed the role of L-tyrosine in the normal synthesis of catecholamines for the general population with a favourable outcome in a previous opinion under Article 13(1) of Regulation (EC) No 1924/2006. The Panel notes that L-tyrosine is the starting point for the synthesis of all catecholamines, including dopamine.

The applicant identified three human intervention studies and one *in vitro* study as pertinent to the health claim. The Panel considers that the references cited do not provide any additional data for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of L-tyrosine in a protein adequate diet and contribution to normal synthesis of dopamine. However, no evidence has been provided that the protein supply in the diet of the European population is not sufficient to fulfil this function of the amino acid.

The Panel considers that the following wording reflects the scientific evidence: “L-tyrosine contributes to normal synthesis of dopamine”.

In order to bear the claim a food should be at least a source of protein as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

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BACKGROUND

Regulation (EC) No 1924/2006³ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health), which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Art 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA:

- The application was received on 26/04/2011.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- The scientific evaluation procedure started on 30/04/2011.
- During the meeting on 30/06/2011 the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to L-tyrosine and contribution to normal synthesis of dopamine.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: L-tyrosine and "is essential for the natural formation of dopamine".

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of L-tyrosine, a positive assessment of its safety, nor a decision on whether L-tyrosine is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

³ European Parliament and Council (2006). Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Vitabiotics Ltd., 1 Apsley way, London NW2 7HF, UK.

Food/constituent as stated by the applicant

According to the applicant, the food constituent for which the claim is made is L-tyrosine.

Health relationship as claimed by the applicant

According to the applicant, L-tyrosine is essential for the natural formation of dopamine.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "L-tyrosine is essential for the natural formation of dopamine".

Specific conditions of use as proposed by the applicant

According to the applicant, the daily requirement of L-tyrosine is dependent on weight and amounts to 1000 mg per day for people that weigh 50 kg, rising to 2000 mg per day for people that weigh 100 kg. The conditions of use proposed by the applicant are 2000 mg per day, consumed preferably after a main meal.

The target population is the general adult population.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is L-tyrosine.

L-Tyrosine is a conditionally indispensable amino acid, which occurs naturally in foods mainly as part of proteins. Dietary L-tyrosine is provided by mixed dietary protein intakes from different sources. It can also be consumed in the form of food supplements as L-tyrosine. The content of L-tyrosine in foods can be measured by established methods.

The Panel considers that the food constituent, L-tyrosine, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is "essential for the natural formation of dopamine". The target population as proposed by the applicant is the general adult population.

The Panel considers that contribution to normal synthesis of dopamine is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The Panel has already addressed the role of L-tyrosine in the normal synthesis of catecholamines for the general population with a favourable outcome in a previous opinion under Article 13(1) of

Regulation (EC) No 1924/2006 (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011). The Panel notes that L-tyrosine is the starting point for the synthesis of all catecholamines, including dopamine. L-Tyrosine is hydroxylated to form dihydroxy-L-phenylalanine (also known as levodopa or L-dopa) via the enzyme tyrosine hydroxylase. In dopaminergic neurons, L-dopa is metabolised to dopamine by means of the enzyme dopa decarboxylase (Friedhoff and Silva, 2002).

According to the applicant, a literature search in PubMed using search terms “tyrosine”, “L-dopa” and “dopamine” was performed with no exclusion criteria.

The applicant identified three human intervention studies and one *in vitro* study as pertinent to the health claim. The Panel considers that the references cited do not provide any additional data for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has been established between the consumption of L-tyrosine in a protein adequate diet and contribution to normal synthesis of dopamine. However, no evidence has been provided that the protein supply in the diet of the European population is not sufficient to fulfil this function of the amino acid.

4. Panel’s comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: “L-tyrosine contributes to normal synthesis of dopamine”.

5. Conditions and restrictions of use

The Panel considers that in order to bear the claim a food should be at least a source of protein as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, L-tyrosine, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “essential for the natural formation of dopamine”. The proposed target population for the health claim is the general adult population. Contribution to normal synthesis of dopamine is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of L-tyrosine in a protein adequate diet and contribution to normal synthesis of dopamine. However, no evidence has been provided that the protein supply in the diet of the European population is not sufficient to fulfil this function of the amino acid.
- The following wording reflects the scientific evidence: “L-tyrosine contributes to normal synthesis of dopamine”.
- In order to bear the claim a food should be at least a source of protein as per Annex to Regulation (EC) No 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on L-tyrosine and contribution to normal synthesis of dopamine pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0298_UK). April 2011. Submitted by Vitabiotics Ltd.

REFERENCES

- EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. Scientific Opinion on the substantiation of health claims related to L-tyrosine and contribution to normal synthesis of catecholamines (ID 1928), increased attention (ID 440, 1672, 1930), and contribution to normal muscle function (ID 1929) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 9(6):2270, 16 pp.
- Friedhoff AJ and Silva R, 2002. Catecholamines. In: Encyclopedia of the human brain. Ed Ramachandran VS. Elsevier Science Academic Press, San Diego, CA, 595-602.